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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-240-4500
FAX: 504-240-4566

September 22, 1999

WARNING LETTER NO. 99-NOL-45

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Carl Haring, Jr., President
Haring's Pride Catfish
681 Pete Haring Road
Wisner, Louisiana 71378

Dear Mr. Haring:

On July 1 & 2, 1999, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your catfish processing facility, located at 681 Pete Haring Road, Wisner, Louisiana. The inspection was conducted to determine compliance with FDA's seafood processing regulations, Title 21, *Code of Federal Regulations* (CFR), Part 123 and the Current Good Manufacturing Practice (CGMP) regulations for foods CFR, Part 110. Our investigator documented numerous deviations from these regulations. This causes your fresh frozen catfish products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act.

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the July 1999 inspection, the FDA investigator observed shortcomings in your system that were similar to those pointed out in the September 2 & 3, 1998, inspection and stated in the untitled letter sent to your firm on July 14, 1998. The FDA investigator also provided your firm with a copy of the Domestic Seafood HACCP Report (Form FDA 3501) and the Form FDA 483, which presents his evaluation of your firm's performance regarding various aspects of the HACCP and CGMP requirements. The Form FDA 483 is enclosed for your review. You have

not met the requirements of Title 21, CFR, Part 123.6(b) to implement your HACCP plan for hazards such as aquaculture drugs and metal fragments as follows:

- There were no receiving logs for three different catfish farmers to document that aquacultured catfish, received at both the firm's plants, come from catfish farmers who have signed a Farmer's Compliance Statement regarding proper aquaculture drug use;

- There were no receiving logs from June 25 to July 1, 1999, for any catfish farmers; and,

- Your firm did not take appropriate corrective action when, on three separate occasions between June 23 and June 29, 1999, metal equipment [redacted] broke during production and the only corrective action performed by your firm was to change the broken part. Your firm did not scan fish products for metal particles as required by your HACCP plan, as required by Title 21, CFR, Part 123.7(b) and (c).

Objectionable equipment and insanitary conditions as listed on Form FDA 483 and Form FDA 3501 are an indication that sanitation monitoring [21 CFR, Part 123.11(b)] at your firm is inadequate. Calling your attention to the objectionable insanitary conditions in this letter is in the interest of having your firm improve its sanitation program consistent with the HACCP principles. A failure to make appropriate corrections could cause your HACCP processing system to be found unacceptable during a future FDA inspection. The noted objectionable insanitary conditions include the following:

- Black residue was encrusted on a water hose submerged in the ice water tank beneath the conveyor belt exiting the [redacted]. Water from this tank was [redacted] onto IQF catfish products to form a glaze. Plastic water pipes above the water tank had brownish residues and were dripping into the water tank;

- Four blue plastic totes holding skinned, "collarboned" catfish were cracked at the sides and bottom with pieces of plastic missing. One tote rested on the floor and another tote rested directly on a wood pallet. Catfish inside these two totes contacted the floor and the pallet. Nine blue plastic totes had rough, abraded surfaces with residues embedded in them; and,

- Water steadily dripped from the plastic covering over the ice auger onto ice in a bin by the whole gutted catfish processing area. Greenish residue was on the pipe where the water formed and dripped onto the ice.

As the principal corporate officer, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that adequate policies and procedures are implemented to prevent a recurrence of the problems.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the applicable regulations. You should take prompt action to correct these deviations. Failure to promptly correct the deviations may result in regulatory action without further notice. These include seizure and/or injunction.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. Our investigator documented this commitment by annotation of the FDA Form 483. You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply, relating to these concerns, should be addressed to the U.S. Food and Drug Administration, Attention: Nicole F. Hardin, Compliance Officer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. If you have any questions regarding the implementation of the HACCP regulations, you may contact Ms. Hardin at the above address or at 504-240-4519.

Sincerely,

James E. Gamet
District Director
New Orleans District

Enclosure: Form FDA 483